HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	HB 1241	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Plasencia; Campbell and others	117 **Y's**	0 **N's**
COMPANION BILLS:	CS/SB 152	**GOVERNOR'S ACTION:**	Approved

SUMMARY ANALYSIS

HB 1241 passed the House on March 2, 2016. The bill was amended by the Senate on March 3, 2016, and subsequently passed the House on March 9, 2016.

Florida law authorizes a supervising physician to delegate to a physician assistant (PA) the authority to order medicinal drugs for the physician's patient who is in a hospital, ambulatory surgical center, or mobile surgical facility. However, there is no authority under Florida law for a physician to delegate equivalent authority to an advanced registered nurse practitioner (ARNP).

The bill expressly authorizes an ARNP to order any medication for administration to a patient in a hospital, ambulatory surgical center, mobile surgical center, or nursing home, within the framework of an established protocol. The bill expands the current ability of a physician to delegate authority to a PA to order medicinal drugs, to allow a PA to order medicinal drugs for a patient in a nursing home.

The bill amends the Florida Comprehensive Drug Abuse Prevention and Control Act to reflect these changes in the practice acts.

Currently, a physician may prescribe and dispense, and a pharmacist may dispense, an emergency opioid antagonist to patients and caregivers to store, possess, and administer to a person believed in good faith to be experiencing an opioid overdose. The bill authorizes a pharmacist to dispense an emergency opioid antagonist pursuant to a non-patient-specific standing order for an autoinjection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use

The bill may have an indeterminate, negative fiscal impact on the Department of Health and has no fiscal impact on local governments.

The bill was approved by the Governor on March 25, 2016, ch. 2016-145, L.O.F., and will become effective on July 1, 2016.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Present Situation

Physician Assistants

Licensure and Regulation

Physician assistant (PA) licensure in Florida is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs and the Florida Council on Physician Assistants (Council) regulates them.[1] PAs are also regulated by either the Florida Board of Medicine for PAs licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. The duty of a board and its members is to make disciplinary decisions concerning whether a doctor or PA has violated the provisions of his or her practice act.[2] There are 7,987 PAs who hold active licenses in Florida.[3]

To be licensed as a PA in Florida, an applicant must demonstrate to the Council:

- Satisfactory passage of National Commission on Certification of Physician Assistants exam;
- Completion of an application and remittance of the applicable fees; [4]
- Completion of an approved PA training program;
- A sworn statement of any prior felony convictions;
- A sworn statement of any previous revocation or denial of licensure in any state;
- Two letters of recommendation; and
- If the applicant is seeking prescribing authority, a copy of course transcripts and the course description from a PA training program describing the course content in pharmacotherapy.[5]

Licenses are renewed biennially.[6] At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.[7] If a PA is licensed as a prescribing PA, an additional 10 hours of continuing medical education in the specialty areas of his or her supervising physician must be completed.[8]

Supervision of PAs

A PA may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.[9] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[10]

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[1] The Council consists of three physicians who are members of the Board of Medicine; one member who is a member of the Board of Osteopathic Medicine, and a physician assistant appointed by the State Surgeon General. (ss. 458.347(9) and 459.022(8), F.S.)
[2] SS. 458.347(12) and 459.022(12), F.S.
[3] Email correspondence with the Department of Health, Medical Quality Assurance staff on November 9, 2015. The number of active licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.
[4] The application fee is $100 and the initial license fee is $200. Applicants must also pay an unlicensed activity fee of $5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[5] SS. 458.347(7) and 459.022(7), F.S.
[6] For timely renewed licenses, the renewal fee is $275 and the prescribing registration fee is $150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of $5. Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[7] SS. 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.
[8] Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C.
[9] SS. 458.347(2)(f) and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[10] Rules 64B8-30.012 and 64B15-6.010, F.A.C.

The supervising physician is responsible and liable for any and all acts of the PA and may not supervise more than four PAs at any time.[11]

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of a supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.[12] Whether the supervision of the PA is adequate is dependent on the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[13]

The decision to permit a PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[14] Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.[15] Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.[16]

Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physician's ability to delegate certain tasks. Prescribing, dispensing, or compounding medicinal drugs and making a final diagnosis are not permitted to be delegated to a PA, except when specifically authorized by statute.[17]

A supervising physician may delegate to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice, except controlled substances, general anesthetics, and radiographic contrast materials;[18]
- Order medicinal drugs for a hospitalized patient of the supervising physician;[19] and
- Administer a medicinal drug under the direction and supervision of the physician.

[11] SS. 458.347(3) and 459.022(3), F.S.
[12] Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.
[13] Id.
[14] Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.
[15] Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.
[16] Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.
[17] Supra note 12.
[18] SS. 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., direct the Council to establish a formulary listing of the medicinal drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008 and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal, or epidural anesthetics, and radiographic contrast materials.
[19] SS. 458.347(4)(g), and 459.022(4)(f), F.S., provides that an order is not a prescription.

Advanced Registered Nurse Practitioners

Licensure and Regulation

Part I of ch. 464, F.S., governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the DOH and are regulated by the Board of Nursing.[20] There are 22,003 actively licensed ARNPs in Florida.[21]

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice and may practice as a certified registered nurse anesthetist, a certified nurse midwife, or a nurse practitioner.[22] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include the performance of advanced-level nursing acts approved by the Board of Nursing, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.[23]

Florida recognizes three types of ARNPs: nurse anesthetist, certified nurse midwife, and nurse practitioner. The Board of Nursing, created by s. 464.004, F.S., establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.[24] To be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master's degree; and
- Submit proof to the Board of Nursing of holding a current national advanced practice certification obtained from a board-approved nursing specialty board.[25]

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.[26] An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.[27] An ARNP must have professional liability coverage of at least $100,000 per claim with a minimum annual aggregate of at least $300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as the beneficiary, in the amount of at least $100,000 per claim with a minimum aggregate availability of at least $300,000.[28]

Supervision of ARNPs

Pursuant to s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in an established protocol filed with the Board of Nursing that is filed within 30 days of entering into a supervisory relationship with a physician and upon biennial license renewal.[29] Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician's primary

[20] Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years; three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one ARNP, one nurse educator of an approved program, and one nurse executive.
[21] E-mail correspondence with the Department of Health (Nov. 9, 2015) (on file with committee staff). This number includes all active licenses, including out of state practitioners.
[22] S. 464.003(3), F.S.
[23] S. 464.003(2), F.S.
[24] S. 464.012(2), F.S.
[25] S. 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.
[26] S. 456.048, F.S.
[27] Rule 64B9-4.002(5), F.A.C.
[28] Id.
[29] Physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. *See* ss. 458.348 and 459.025, F.S.

practice location.[30] If the physician provides specialty health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes;
- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.[31]

To ensure appropriate medical care, the number of ARNPs a physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures;
- Practice setting; and
- Availability of the supervising physician or dentist.[32]

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty;
- Perform medical acts authorized by a joint committee; and
- Perform additional functions determined by rule. [33]

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.[34] Certified registered nurse anesthetists are permitted to order certain controlled substances "to the extent authorized by an established protocol approved by the medical staff of the facility in which the anesthetic service is performed."[35]

ARNP Petition for Declaratory Statement

On January 22, 2014, a petition for declaratory statement[36] was filed with the Board of Nursing that asked, in substance, whether an ARNP can legally order narcotics for patients treated within an

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[30] S. 458.348(4) and 459.025(3), F.S.
[31] S. 458.348(4)(e), and 459.025(3)(e), F.S.
[32] Rule 64B9-4.010, F.A.C.
[33] S. 464.012(3), F.S.; pursuant to s. 464.012(4), F.S., certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform additional acts that are within their specialty and authorized under an established supervisory protocol.
[34] SS. 893.02(21) and 893.05(1), F.S. The definition of practitioner does not include ARNPs.
[35] S. 464.012(4), F.S.
[36] Pursuant to s. 120.565(1), F.S., a declaratory statement is an agency's opinion regarding the applicability of a statutory provision, rule, or agency order to a petitioner's set of circumstances.

institution with written protocols from an attending physician.[37] The petition noted that prior to January 2014, ARNPs ordered controlled substances for patients.[38] Effective January 2014, a hospital disallowed the practice and required all ARNPs to get an order from a physician. The hospital cited passage of legislation in 2013,[39] which clarified the authority of PAs to order controlled substances for patients in institutions, but did not address the authority of ARNPs.[40] The Board of Nursing dismissed the petition, finding that it failed to comply with the requirements of Chapter 120, F.S., and that it sought an opinion regarding the scope of practice of a category of licensees based on an employer's policies.[41]

Florida Comprehensive Drug Abuse Prevention and Control Act

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules.[42] The distinguishing factors between the different drug schedules are the "potential for abuse" of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.[43]

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.[44]

A health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.[45] The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only engage in those activities authorized under state law for the jurisdiction in which their practice is located.[46]

The DEA exempts certain agents and employees from registration with the agency, including an individual practitioner[47] who is an agent or an employee of a hospital or other institution. Such practitioner may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or institution, provided that:

- Such dispensing, administering, or prescribing is done in the usual course of his or her professional practice;
- Such practitioner is authorized to do so by the jurisdiction in which he or she is practicing;

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[37] *In Re: Petition for Declaratory Statement of Carolann Robley, ARNP*, 40 Fla. Admin. Reg. 81 (Apr. 25, 2014).
[38] For a copy of the petition for declaratory statement and the final order disposing the petition, please see http://www.floridahealth.gov/licensing-and-regulation/declaratory/_documents/nursing/DOH-14-0732-DS-MQA.pdf#page=1&zoom=auto,-10,795 (last visited March 15, 2016).
[39] Ch. 2013-127, L.O.F.
[40] Supra note 37.
[41] *In Re: Petition for Declaratory Statement of Carolann Robley, ARNP*, 40 Fla. Admin. Reg. 103 (May 28, 2014).
[42] See s. 893.03, F.S.
[43] SS. 893.04 and 893.05, F.S.
[44] Drug Enforcement Administration, *About Us*, available at http://www.deadiversion.usdoj.gov/Inside.html (last visited March 15, 2016).
[45] Registration numbers must be renewed every three years. Drug Enforcement Administration, *Practitioners Manual*, 7(2006), available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited March 15, 2016).
[46] Id.
[47] An individual practitioner is defined as a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States of the jurisdiction in which he or she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. (21 C.F.R. s. 1300.01(b)).

- The hospital or institution employing the practitioner has verified that the practitioner is authorized to dispense, administer, or prescribe drugs within the jurisdiction;
- Such individual is acting only within the scope of his or her employment in the hospital or institution;
- The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized; and
- The hospital or institution maintains a current list of internal codes and the corresponding individual practitioners that is available at all times to other registrants and law enforcement agencies for the purpose of verifying the prescribing authority of the individual practitioners.[48]

An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner)[49] registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of a prescription)[50] controlled substances if and to the extent authorized by state law, under the registration of the employer or principal practitioner in lieu of being registered himself or herself.[51]

Opioids

The drug overdose death rate involving opioids has increased by 200% since 2000 and has now become the leading cause of accidental deaths in the United States.[52] In 2014, there were 47,055 drug overdose deaths in the United States of which 28,647 (61%) involved some type of opioid.[53] In Florida, 2,922 deaths were attributable to prescription opioids in 2014.[54]

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.[55] They are commonly used as pain relievers to treat acute and chronic pain. An individual experiences pain as a result of a series of electrical and chemical exchanges among his or her peripheral nerves, spinal cord, and brain.[56] Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.[57] When an individual experiences pain, the body releases hormones, such as endorphins, which bind with targeted opioid receptors.[58] This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.[59] Opioids function in the same way by binding to specific opioid

[48] 21 C.F.R. s. 1301.22(c).
[49] Examples of mid-level practitioners include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.
[50] The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting. See 21 C.F.R. s. 1300.01(b).
[51] 21 C.F.R. s. 1301.22(b).
[52] Centers for Disease Control and Prevention, *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014,* Morbidity and Mortality Weekly Report (MMWR) 64(50); 1378-82, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w (last visited March 14, 2016).
[53] Id.
[54] Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners, 2014 Annual Report* (Sept. 2015). *available at* https://www.fdle.state.fl.us/Content/Medical-Examiners-Commission/MEC-Publications-and-Forms/Documents/2014-Annual-Drug-Report-FINAL.aspx (last visited March 14, 2016).
[55] World Health Organization, *Information Sheet on Opioid Overdose*, World Health Organization (Nov. 2014), *available at* http://www.who.int/substance_abuse/information-sheet/en/ (last visited March 14, 2016).
[56] Mayo Clinic Health Library, *How You Feel Pain*, (Feb. 2009), *available at* http://www.riversideonline.com/health_reference/Nervous-System/PN00017.cfm (last visited March 14, 2016).
[57] Gjermund Henriksen, Frode Willoch; *Brain Imaging of Opioid Receptors in the Central Nervous System,* (2008) 131 (5): 1171-1196.
[58] Id.
[59] Id.

receptors in the brain, spinal cord, and gastrointestinal tract, thereby reducing the perception of pain.[60] Opioids include[61]:

- Buprenorphine (Subutex, Suboxone)
- Codeine
- Fentanyl (Duragesic, Fentora)
- Heroin
- Hydrocodone (Vicodin, Lortab, Norco)
- Hydromorphone (Dilaudid, Exalgo)
- Meperidine
- Methadone
- Morphine
- Oxycodone (OxyContin, Percodan, Percocet)
- Oxymorphone
- Tramadol

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.[62] Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward, which can lead to abuse.[63] Continued use of these drugs can lead to the development of tolerance and psychological and physical dependence.[64] This dependence is characterized by a strong desire to take opioids, impaired control over opioid use, persistent opioid use despite harmful consequences, a higher priority given to opioid use than to other activities and obligations, and a physical withdrawal reaction when opioids are discontinued.[65]

An overabundance of opioids in the body can lead to a fatal overdose. In addition to their presence in major pain pathways, opioid receptors are also located in the respiratory control centers of the brain.[66] Opioids disrupt the transmission of signals for respiration in the identical manner that they disrupt the transmission of pain signals. This leads to a reduction, and potentially cessation, of an individual's respiration. Oxygen starvation will eventually stop vital organs like the heart, then the brain, and can lead to unconsciousness, coma, and possibly death.[67] Within 3-5 minutes without oxygen, brain damage starts to occur, soon followed by death.[68] However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.[69] An opioid overdose can be identified by a combination of three signs and symptoms referred to as the "opioid overdose triad": pinpoint pupils, unconsciousness, and respiratory depression.[70]

Opioid Antagonist

An opioid antagonist is a drug that blocks the effects of exogenously administered opioids. Opioid antagonists are used in opioid overdoses to counteract life-threatening depression of the central

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[60] Department of Health and Human Services- Substance Abuse and Mental Health Services Administration, *SAMHSA Opioid Overdose Toolkit: Facts for Community Members* (2013, rev. 2014) 3, *available at* https://store.samhsa.gov/shin/content/SMA14-4742/Toolkit_Community.pdf (last visited March 14, 2016).
[61] Supra note 54.
[62] Supra note 55.
[63] National Institute on Drug Abuse, *How Do Opioids Affect the Brain and Body?* (rev. Nov. 2014), *available at* http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body (last visited March 14, 2016).
[64] Supra note 57.
[65] Supra note 55.
[66] K.T.S. Pattinson, *Opioids and the Control of Respiration*, British Journal of Anaesthesia, Volume 100, Issue 6, pp. 747-758, *available at* http://bja.oxfordjournals.org/content/100/6/747.full (last visited March 14, 2016).
[67] Harm Reduction Coalition*, Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects* (Fall 2012), http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf (last visited March 14, 2016).
[68] Id. at 9.
[69] Id. at 9.
[70] Supra note 55.

nervous system and respiratory system, allowing an overdose victim to breathe normally.[71] This occurs because opioid antagonists create a stronger bond with opioid receptors than opioids. This forces the opioids from the opioid receptors and allows the transmission of signals for respiration to resume.[72] This effect lasts only for a short period of time[73] with the narcotic effect of the opioids returning if still present in large quantities in the body. In this scenario, additional doses of an opioid antagonist would be required and it is why it is generally recommended that anyone who has experienced an overdose seek medical attention.

Community-based opioid antagonist prevention programs can be successful in increasing the number of opioid overdose reversals. Opioid antagonists were originally prescribed and distributed only to emergency personnel (EMTs, firefighters and law enforcement). In 1996, community-based programs began offering opioid antagonists and other opioid overdose prevention services, in states authorizing such activities, to persons who use drugs, their families and friends and service providers (health care providers, homeless shelters, and substance abuse treatment programs).[74] In October 2010, a national advocacy and capacity-building organization surveyed 50 programs known to distribute opioid antagonists in the United States, to collect data on various issues including overdose reversals.[75] Forty-eight programs responded to the survey and reported training and distributing opioid antagonists to 53,032 persons and receiving reports of 10,171[76] overdose reversals.[77] Based upon these findings, the report concluded that providing opioid overdose education and opioid antagonists to persons who use drugs and to persons who might be present at an opioid overdose can help reduce opioid overdose mortality.[78]

In 2015, Florida enacted the Emergency Treatment and Recovery Act (act), which authorized patients and caregivers[79] to store, possess, and administer an emergency opioid antagonist[80] to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.[81] This authorization only applies in an emergency when a physician is not immediately available. The act authorized health care practitioners to prescribe and dispense, and pharmacists to dispense, an emergency opioid antagonist. The act also authorized emergency responders to possess, store, and administer approved emergency opioid antagonists.

Additionally, individuals possessing, administering, prescribing, dispensing, or storing an approved opioid antagonist in compliance with law are immune from civil liability; and health care practitioners and pharmacists are immune from civil or criminal liability related to the prescribing or dispensing of an emergency opioid antagonist if the practitioner complies with the law, acts in good faith, and exercises reasonable care.

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[71] Harm Reduction Coalition, *Understanding Naloxone, available at* http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited March 14, 2016).
[72] Supra note 57 at pg. 11.
[73] Supra note 57 at pg. 72. The half-life for a common opioid antagonist in adults ranged from 30 to 81 minutes. Acute opiate withdrawal is a potential side effect of naloxone; however, this would be time limited to the half-life of naloxone.
[74] Centers for Disease Control and Prevention, *Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010*, Morbidity and Mortality Weekly Report (MMWR), 61(06);101-105, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm (last visited March 14, 2016).
[75] Id.
[76] Id. The findings in this report are subject to at least three limitations. First, other opioid antagonist distribution programs might exist that were unknown to the national advocacy group. Second, all data is based on unconfirmed self-reports from the 48 responding programs. Finally, the numbers of persons trained in opioid antagonist administration and the number of overdose reversals involving opioid antagonists likely were underreported because of incomplete data collection and unreported overdose reversals. However, because not all untreated opioid overdoses are fatal, some of the persons with reported overdose reversals likely would have survived without opioid antagonist administration.
[77] Id.
[78] Id.
[79] Caregivers include family members, friends, or persons having recurring contact with a person at risk of experiencing an opioid overdose.
[80] The act defines an emergency opioid antagonist as naloxone hydrochloride or any similarly acting drug that blocks the effects of exogenously administered opioids and is approved by the United States Food and Drug Administration for the treatment of opioid overdose.
[81] Ch. 2015-123, L.O.F, codified at s. 381.887, F.S.

Effect of Bill

Currently, a PA may order any medication for administration to a patient of his or her supervising physician in a hospital, ambulatory surgical center, or mobile surgical facility. The bill adds authority for a PA to order medication for administration in a nursing home.

The bill, under the “Barbara Lumpkin Prescribing Act,” authorizes an ARNP to order any medication, including a controlled substance, for administration to a patient, within the framework of an established protocol, in a facility licensed under ch. 395, F.S. (a hospital, ambulatory surgical center, or mobile surgical facility), or part II of ch. 400, F.S. (a nursing home).

The bill amends the Florida Comprehensive Drug Abuse Prevention and Control Act to expressly provide that a licensed practitioner may authorize a licensed PA or ARNP, who he or she supervises, to order controlled substances for administration to a patient in a hospital, ambulatory surgical center, mobile surgical facility, or nursing home.

The bill authorizes a pharmacist to dispense an emergency opioid antagonist pursuant to a non-patient-specific standing order for an autoinjection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use.

The bill reenacts several sections of Florida law for the purpose of incorporating amendments made by the bill.

The bill provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill may have an indeterminate, negative fiscal impact on the DOH due to a possible increase in practitioner complaints associated with the ARNPs’ and PAs’ new authority to order medications for administration in new settings.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Physicians or institutions who use ARNPs or PAs to order the administration of medications for hospitalized patients or those in nursing homes may realize cost savings associated with increased efficiencies of using such practitioners. Additionally, patients may be better served by ARNPs and PAs

who can order medications for administration under a supervisory protocol, without the direct involvement of the supervising physician.

Individuals at risk of experiencing an opioid overdose will have greater access to an emergency opioid antagonist since a patient-specific prescription for such medication to be dispensed is no longer necessary.

D. FISCAL COMMENTS:

None.